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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/815,242

03/21/2001

Robert Haselbeck

ELITRA.011A

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02/22/2006

MERCK AND CO., INC

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RAHWAY, NJ 07065-0907

EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 09/815,242	Applicant(s) HASELBECK ET AL.	
	Examiner Terra C. Gibbs	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 17 January 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 12,31,45-69,77-87,89-96,100,101,103 and 104.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

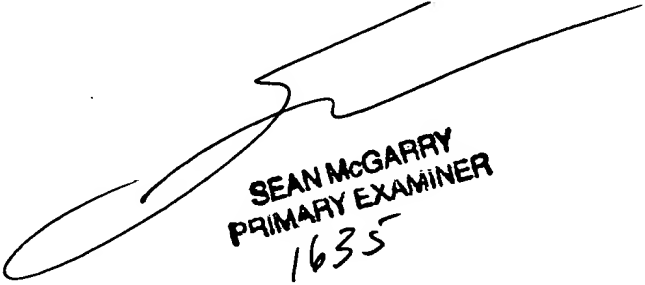
8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: At the outset, it is noted that claims 77, 87, 100, and 104 contain sequences that have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. The request for reconsideration has been fully considered, but does not place the application in condition for allowance because claims 78-84 would remain rejected under 35 U.S.C. 112, first paragraph rejection as failing to comply with the written description requirement. In response to this rejection, Applicants argue that the claims do not merely recite a sought after property, but the claims also provide a generic structural description of antisense oligonucleotides based on SEQ ID NO:1463. Applicants contend that reference to antisense activity provides a functional description that further limits the overall provided structure of the nucleic acid. Applicants argue that since structural and functional descriptions have been provided, the skilled artisan need only perform routine testing of sequences within the overall structure indicated in the claims to confirm that such sequences have the desired antisense activity. Applicant's arguments and contentions have been fully considered but are not found persuasive. As argued in the previous Office Action mailed October 19, 2005, to satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. It is maintained that, while Applicants provide written description for SEQ ID NO:1463, the claims do not support the breadth of any nucleic acids with any particular percent identity to SEQ ID NO:1463 because the claims embrace a very large genus of nucleic acids, where no working examples of any nucleic acids with any particular percent identity to SEQ ID NO:1463 that carry out the functional properties required in the claims have been described. Further, functionality alone as recited in the instant claims to identify the nucleic acid molecules of the claimed method does not elucidate the structure (e.g. nucleic acid sequence) of the nucleic acid molecules having such function. Therefore, in the absence of any teaching by way of structure or reference to active domains or regions, one of skill in the art could not immediately envision those antisense nucleic acids with varying degrees of sequence identity to SEQ ID NO:1463, which retains the function of reducing the activity of a gene product required for cellular proliferation, thereby producing a sensitized cell as recited in the instant claims.

The request for reconsideration has been fully considered, but does not place the application in condition for allowance because claims 12,31,45-69,77-87,89-96,100,101,103 and 104 would also remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9 and 10 of U.S. Patent No. 6,720,139 ('139). In response to this rejection, Applicants argue that whether the '139 patent embraces the methods as instantly claimed, or the present application anticipates the '139 patent, does not establish obviousness-type double patenting for the present claims. Applicants contend that an obviousness-type double patenting analysis generally involves: (1) determining the differences between the claims in the earlier patent and the claims in the later patent; and (2) determining whether the difference renders the claims patentable distinct. Applicants argue that the pending claims differ from the '139 patent claims by providing description of sequences, where the '139 patent claims does not specifically provide such sequences. Applicant's arguments and contentions have been fully considered but are not found persuasive because while the Examiner agrees that the pending claims differ from the '139 patent by providing a description of the sequences (e.g. specific SEQ ID NO), as argued in the previous Office Action mailed October 19, 2005, the '139 patent is drawn to a broad genus of antisense nucleic acids, while the instant claims are drawn to a particular species of antisense nucleic acid, namely SEQ ID NO:1463. Since the species of the instant application anticipates the genus of the claims of the '139 patent, a person of ordinary skill in the art would conclude that the invention defined in the instant application would have been an obvious variation of the invention defined in the patent.



SEAN MCGARRY
PRIMARY EXAMINER
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